DEPARTMENT OF HEALTH AND HUMAN SERVICES 95143d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

December 23, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 - 07

Wesley Thoreson
President
Best Veterinary Solutions, Inc.
1716 Detroit Street
Ellsworth, Iowa 50075

Dear Mr. Thoreson:

This letter references your firm's manufacturing and marketing of MANAGE® PLUS, a product that contains sodium selenium. An FDA inspection of your facility located at 325 Lakeland Drive, NE, Willmar, Minnesota, conducted on May 20, 2004, revealed that your firm is marketing this product in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigator collected a documentary sample for MANAGE® PLUS, including labels, product information sheets, and batch records. On December 7, 2004, Dr. Garthwaite of my office verified with you that your firm is currently selling feed with selenium for the conditions of use set out in the labeling and product information collected during the inspection. Our review of this information reveals that MANAGE® PLUS is adulterated within the meaning of Section 402(a)(2)(C)(i) of the Act because it contains sodium selenite, which is unsafe within the meaning of Section 409(a)(2) of the Act.

The labeling and product information sheet indicate that MANAGE® PLUS is for use as an acidifying agent in drinking water for poultry and swine, and as a source of selenium. The product is, therefore, a food as defined by Section 201(f) of the Act because it is an article used as a component of food or drink for animals. Under the Act, any substance intentionally added to a food must be used in accordance with a food additive regulation, unless the substance is generally recognized as safe (GRAS) among qualified experts for its intended use

in the food. We are not aware of any basis to conclude that the selenium in MANAGE® PLUS is GRAS for use in the drinking water of poultry and swine. The selenium in MANAGE® PLUS is not used in accordance with a food additive regulation. While there is a food additive regulation for selenium in Title 21, Code of Federal Regulations, Section 573.920 (21 CFR 573.920, copy enclosed), the conditions of use of selenium in MANAGE® PLUS do not conform to the conditions of use for selenium described in that regulation. Thus, MANAGE® PLUS is adulterated within the meaning of Section 402(a)(2)(C)(i) because it contains a food additive that is unsafe within the meaning of Section 409(a) of the Act. In addition, MANAGE® PLUS is not labeled appropriately for an animal feed product. For example, the label does not contain an ingredient list, as required by 21 CFR 501.4.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all products manufactured and distributed by your firm comply with the Act. We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Dr. Garthwaite discussed with you some general issues pertaining to the labeling of products marketed by your firm. The Food and Drug Administration's Center for Veterinary Medicine will provide comments from their review of labels for your products.

Please notify this office in writing within 15 working days of the receipt of this letter of the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the date/time frame within which the corrections will be implemented. Your reply should be sent to Dr. Garthwaite at the address on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

BDG/ccl

Enclosure: 21 CFR 573.920